

# Wireless Issues for Home Care Medical Devices

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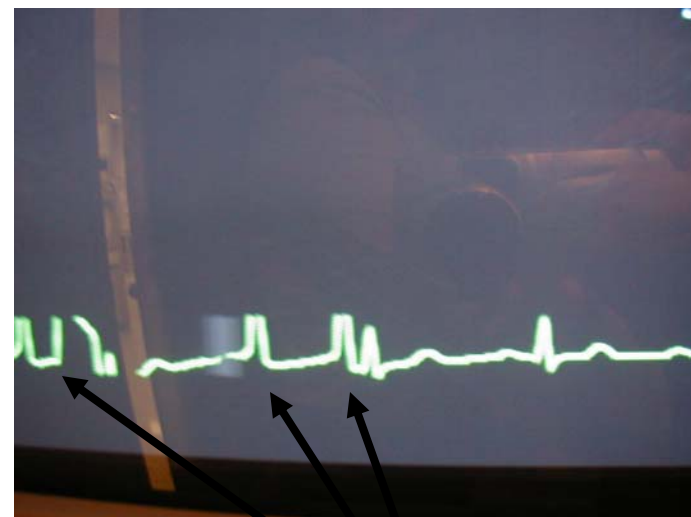


## Medical Device EMI Testing - Blackberry

BB in  
Pocket →



Test Set up



Recorded Interference

HP Sonos 5500 Cardiac Ultrasound



**Making wireless home care medical device safe, effective, and secure requires designing, testing, deploying and managing the device for wireless risks.**



## Overview



- **RF Wireless technology in healthcare**
- **Issues in the home environment**
- **Addressing wireless risks**
- **Challenges and opportunities**

# Wireless Technology

DTV

MedRadio  
(MICS)

WiFi

WMTS

Mobile  
Phones

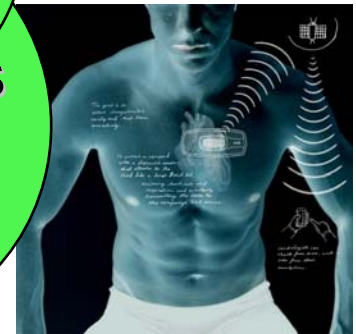
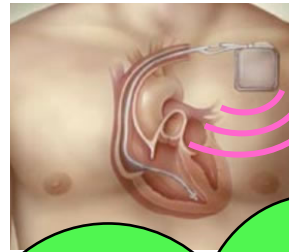
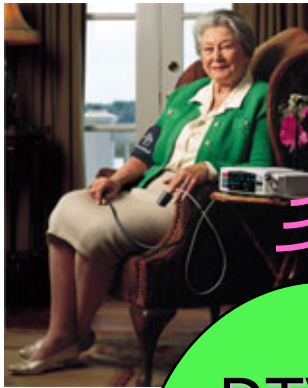
Cognitive  
Radio

RFID

Mobile  
Radio

GPS

WiMax



## Wireless Issues in the Home Environment

- **Home RF Wireless environment is uncontrolled with many wireless emitters in/out of the home environment**
- **Little oversight or technical knowledge**
- **Rapidly changing wireless technology and environment**
- **Wireless is both a source and victim for electromagnetic interference (EMI)**
- **Wireless risks include:**
  - **QoS, data integrity, coexistence, security, EMC**

# Medical Wireless Risk Priorities



**Life critical functions,  
high priority alarms,  
therapy, remote  
control**

**Risk**

**Low priority data, No therapy  
or alarms**

- **Shared risk environment**
- **Risk related to Device/system intended use, use of wireless technology, and data transmitted**
- **Consequences of not getting data across wireless link correctly, timely, and securely**



## Addressing Wireless in Submissions

- **System wireless description**
- **Quality of Service**
- **Wireless Coexistence**
- **Wireless data integrity**
- **Wireless data security**
- **EMC**
- **Labeling**





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## Medical Devices

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## Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE



PDF Printer Version

**This guidance document is being distributed for comment purposes only.**

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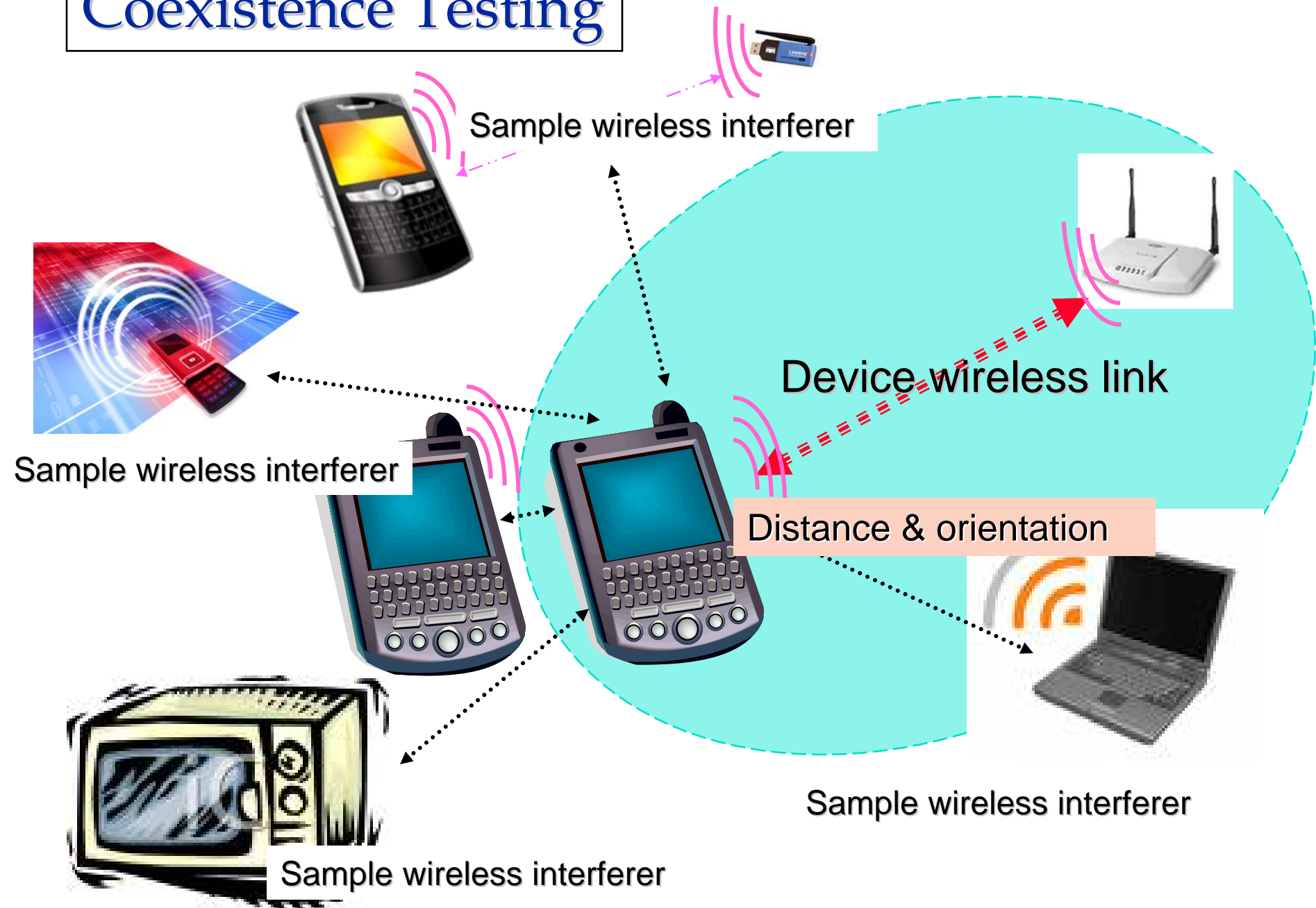
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to <http://www.fda.gov/dockets/ecomments>. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Donald M. Witters Jr. at 301-796-2483, or by e-mail at [Donald.Witters@fda.hhs.gov](mailto:Donald.Witters@fda.hhs.gov).



U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health  
Electrophysics Branch  
Division of Physical Science  
Office of Science and Engineering Laboratories

# Coexistence Testing



## Challenges and Opportunities

- **More home care with more functions and less on-sight management**
- **Changing wireless technology, wider integration, and more use of limited wireless resources**
- **Greater need for shared risk management**
- **Need for information and standards for safe, secure, and reliable medical systems**
- **Opportunity to create products and pathways for wireless home care devices**



## Summary

- **Home environment presents challenges for safe, secure, reliable wireless healthcare**
- **Wireless deployment is rapidly increasing and technology continues to change and evolve**
- **Risk management in a shared risk environment**
- **Lack of adequate tools and clear pathways for safe, secure, and reliable wireless healthcare.**
- **Addressing wireless should include:**
  - Description of wireless technology and characteristics
  - QoS, wireless data integrity, coexistence, wireless security, EMC, labeling

**Making wireless home care devices requires research, risk awareness and management, stakeholder engagement, and a proactive approach to safe, secure, reliable deployment.**



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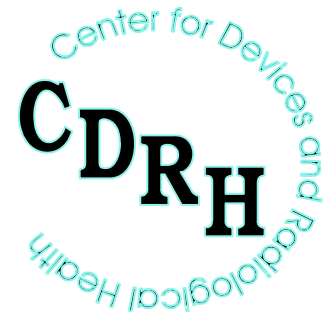
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# CLOSE TO HOME JOHN McPHERSON



Claire discovers that The Clapper operates on the same frequency as Don's pacemaker.

**Why Wireless issues are important.**